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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2015-0422; FRL-9930-32]

Pesticide Cumulative Risk Assessment: Framework for Screening Analysis; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the availability of draft guidance, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis*, for public comment. This document provides guidance on how the EPA will screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs) and conducting cumulative risk assessments (CRA). Additionally, EPA is also seeking comments on a draft copy of the human health risk assessment where the cumulative assessment was conducted in conjunction with pending actions for abamectin.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0422 by one of the following methods:
15P-0187

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Monique Perron, Health Effects Division (7509P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-0395; email address: perron.monique@epa.gov or Don Wilbur, Health Effects Division (7509P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8894; email address: wilbur.donald@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial

Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. What Action is the Agency Taking?

Section 408(b)(2)(D)(v) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to take into account available evidence concerning the cumulative effects of pesticide

residues and other substances that have a common mechanism of toxicity. The Office of Pesticide Programs (OPP) has previously developed two guidance documents:

- *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999), which describes the process for CMGs;
 - *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (USEPA, 2002), which describes the steps used in conducting CRA.
- Copies of those two guidance documents can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2015-0422.

The process described in those documents results in a highly refined CRA but requires an extensive amount of resources, large amounts of toxicology and exposure data, and may involve sophisticated modelling. The process involves developing science policy documents that establish a CMG before conducting a highly refined CRA. To date, OPP has established five CMGs: Organophosphates (OPs), *N*-methyl carbamates (NMCs), chloracetanilides, triazines, and naturally occurring pyrethrins and synthetic pyrethroids. CRAs have been conducted on each group and are available at <http://www.epa.gov/oppsrrd1/cumulative/>.

The level of refinement provided by this approach is not necessary or even feasible for all existing pesticide classes. The 2002 CRA guidance notes that not all cumulative assessments need to be of the same depth and scope and that it is important to determine the need for a comprehensive risk assessment by considering the exposure profile. The 2011 World Health Organization International Programme on Chemical Safety guidance on CRA which are available at <http://www.who.int/ipcs/en> describes a screening approach involving tiered analysis with increasing levels of refinement. The Agency has developed this guidance to assist scientists and

decision-makers in screening pesticides for potential common mechanism groupings and conducting screening-level CRAs, neither of which is provided for in either of the listed guidance documents.

Specifically, the draft *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis*, that the EPA is seeking comment on, provides guidance for screening available information to identify groups of pesticides that may have a common mechanism of toxicity (i.e., candidate CMGs). In addition, this document provides guidance for screening available information on those candidate groups for potential cumulative risks, which may lead to more refined CRAs. This document relies on the policies and principles provided in the CMG and CRA guidance documents along with expertise and knowledge gained by OPP in the conduct of the five referenced CRAs.

Based on the proposed screening guidance, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis*, EPA determined that abamectin and emamectin share a similar toxicological profile and a testable hypothesis can be identified. Thus, EPA has developed a screening level cumulative analysis using highly conservative exposure assumptions. Specifically, dietary and residential exposures were assessed to determine whether there would be any potential cumulative concern.

The cumulative assessment was done in conjunction with pending actions for abamectin to expand the use of abamectin on Caneberry subgroup 13-07A, soybeans, sweet corn, ear tags for lactating dairy cattle, and golf course turf. A draft copy of the human health risk assessment considering both aggregate and cumulative risks is included in the docket to provide an example of how the EPA would implement the, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis*, and to allow for public comment.

Authority: FFDCA § 408(b) [21 U.S.C. 346 a(b)].

Dated: July 17, 2015.

Jack Housenger,

Director, Office of Pesticide Programs.

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